

# ECRI 2007<sup>★</sup>

★ *european conference on research infrastructures*

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# GMP facilities associated with distributed research Infrastructures for biomedical and clinical research

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## Biomedical & Clinical Research

### *The context*

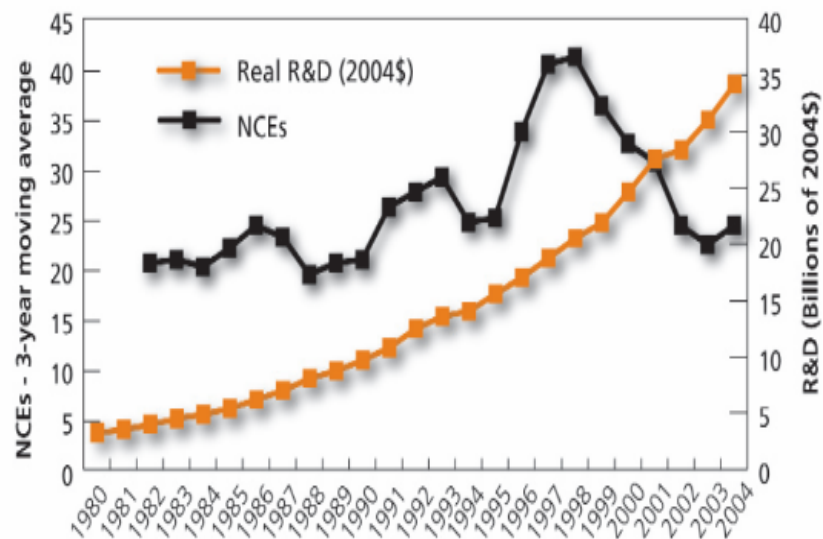
- High social & economical impacts : patients as end-users / Economic actors
- Drug discovery and development of new innovative therapeutic molecules (*IMI - Joint Technology Initiative*)
  - Faster
  - Cost-effectiveness
- Clinical benefit improvements
- Treatment of pathologies with strong unmet needs (Cancer, neurodegenerative diseases, age-related diseases,...)
- Fragmentation of clinical research in Europe

## Biomedical & Clinical Research : *the situation*

Over the past Three decades :

- **Decline** of innovation and R&D productivity in terms of **new chemical/molecular entities (NCE/NME)**
- **Growth** of R&D expenditures per unit of NCE (802 M USD for a new NME in average - 2000)
- **Increase** of time to the market : 11,8 years in average

Figure 2.5 - Comparison of R&D costs versus launch of new chemical entities (NCEs)



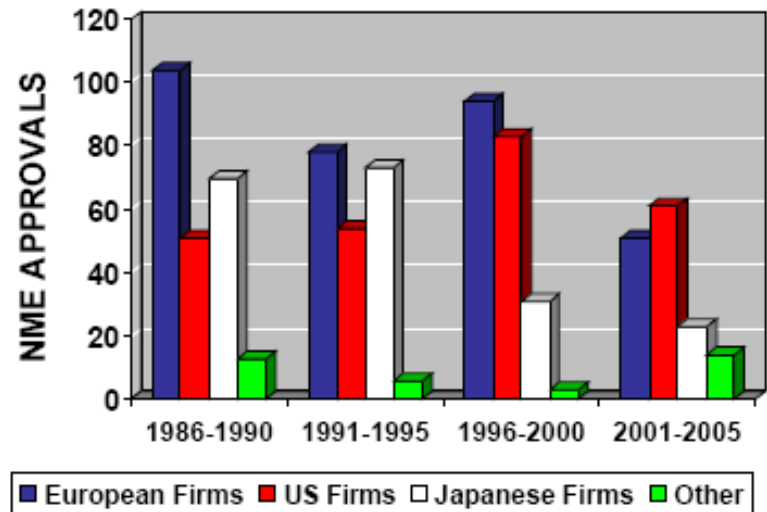
Source: Tufts CSDD Approved NCE Database; PhRMA

# Biomedical & Clinical Research : *the situation*

## Innovative Performance

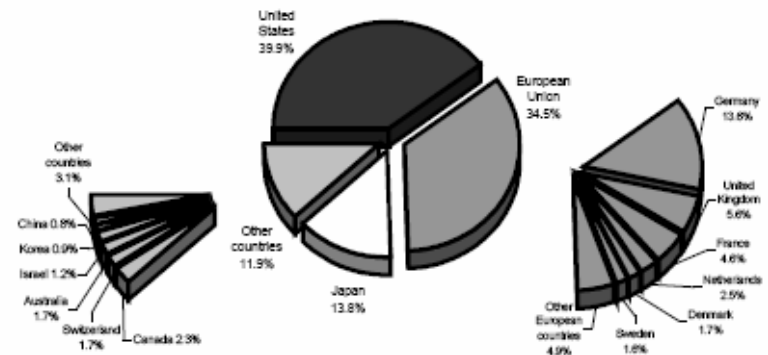
- US firms better than EU or japan firms for NME approvals

Figure 2.14 – NME approvals in Europe, US and Japan



Source: EFPIA

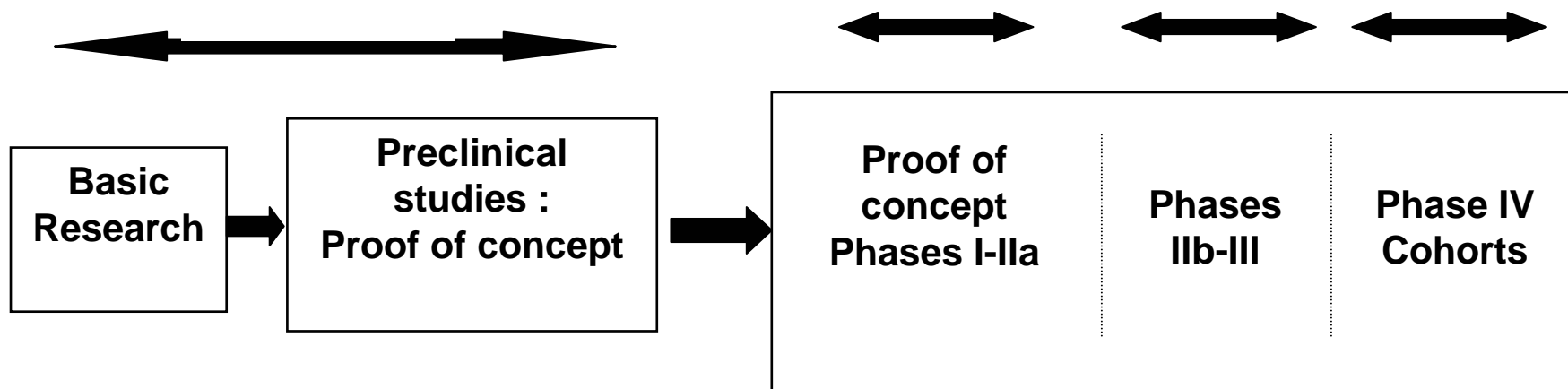
Figure 2.15 – Share of countries' biotechnology patents filed at EPO, 2002



Source – OECD Biotechnology Statistics, 2006

- Patenting: US leads UE

## Drug development, Clinical research & Infrastructures



## Why *infrastructures* for biomedical & clinical research ?

- Patients as : end-users - economic actors - **participants in research (Cohorts - Registries)**
- Health care improvements
- New and Innovative Treatments
- Competitiveness of drug discovery in Europe which requires to work:
  - faster (even with high costs)
  - with high quality data (clinical and **biobanks**)
  - and high quality medicinal products (**GMP**)
  - in compliance with requirements of the EU Directives for protection of patients

## Life Sciences Research Infrastructures in Europe

- **Single-sited infrastructures :**  
Infrastructures for brain mapping, animal models, very high field NMR (Neurospin), Cyclotron
- **Distributed infrastructures :**
  - « omics » platforms
  - Functional investigations and repositories for mice
  - Clinical Research Infrastructures and production of products for biotherapy (*GMP facilities*)
  - Biological Resources Centres - Cohorts of Patients
  
  - Biosafety-level 4 laboratory

## Why *distributed* infrastructures ?

Because ***patients are distributed***

- => Access to patients (limiting rate for faster development of new medicines - Physio-pathological studies, biomarkers, and therapeutic trials) - *distributed EU infrastructures take advantage of the EU population*
- => Distributed EU infrastructures unlock latent scientific and medical competences
- => National regulations on clinical research remain fragmented

*Distributed* research infrastructures :

- 1 – Network of ***Clinical Research Centres*** : high quality clinical data
- 2 – Network of ***GMP facilities*** : high quality Innovative Medical Products
- 3 – Network of ***Biobanks*** : high quality biological data and biomarkers

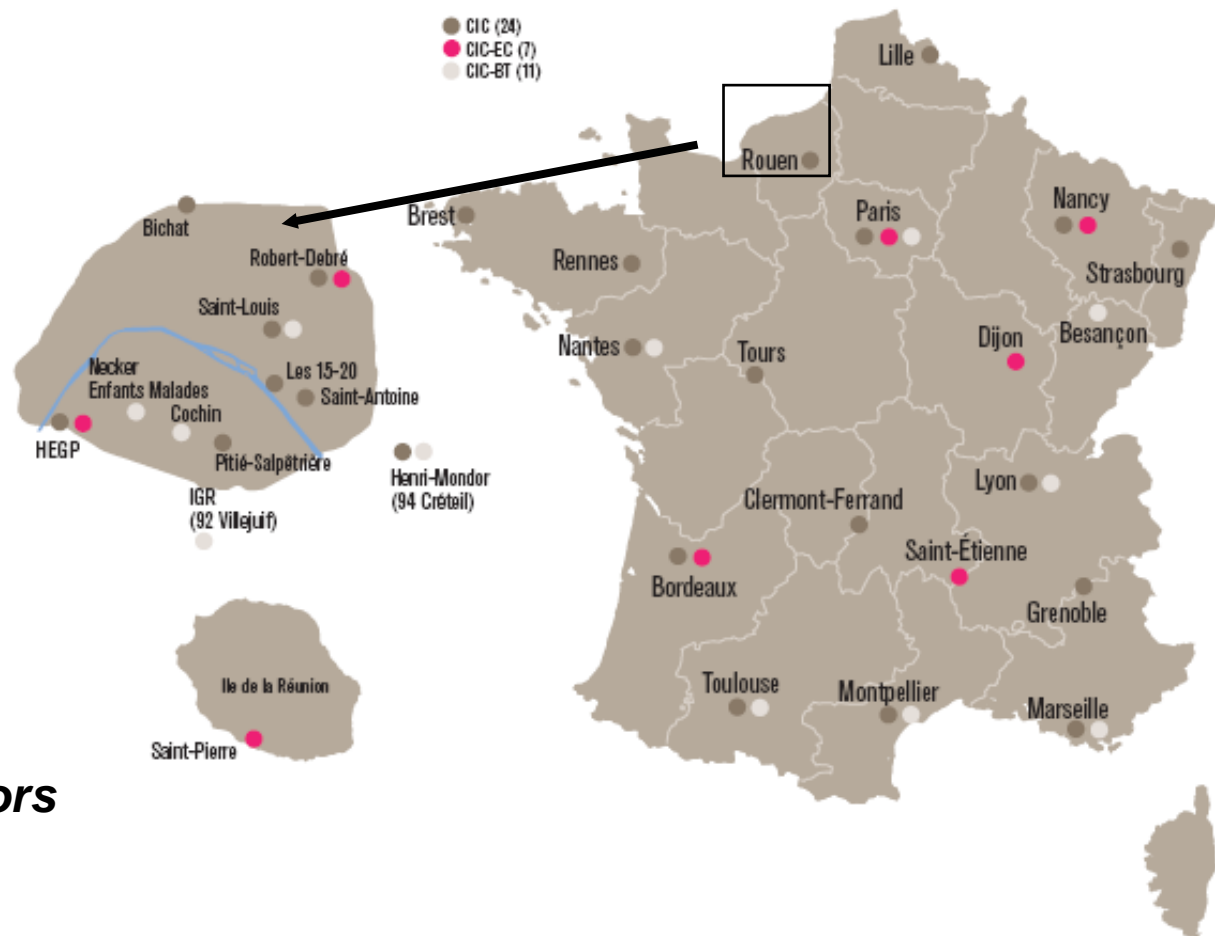
## Architecture of distributed Research Infrastructures

**Local level** : *access to patients*

**Regional-national level** : *based on national-regional regulation and organisation of research*

**EU level** : *allows for EU integration and multinational cooperation (multicentric studies, cohorts)*

## 41 Clinical Investigation Centres



***Access to patients***  
***Support to investigators***

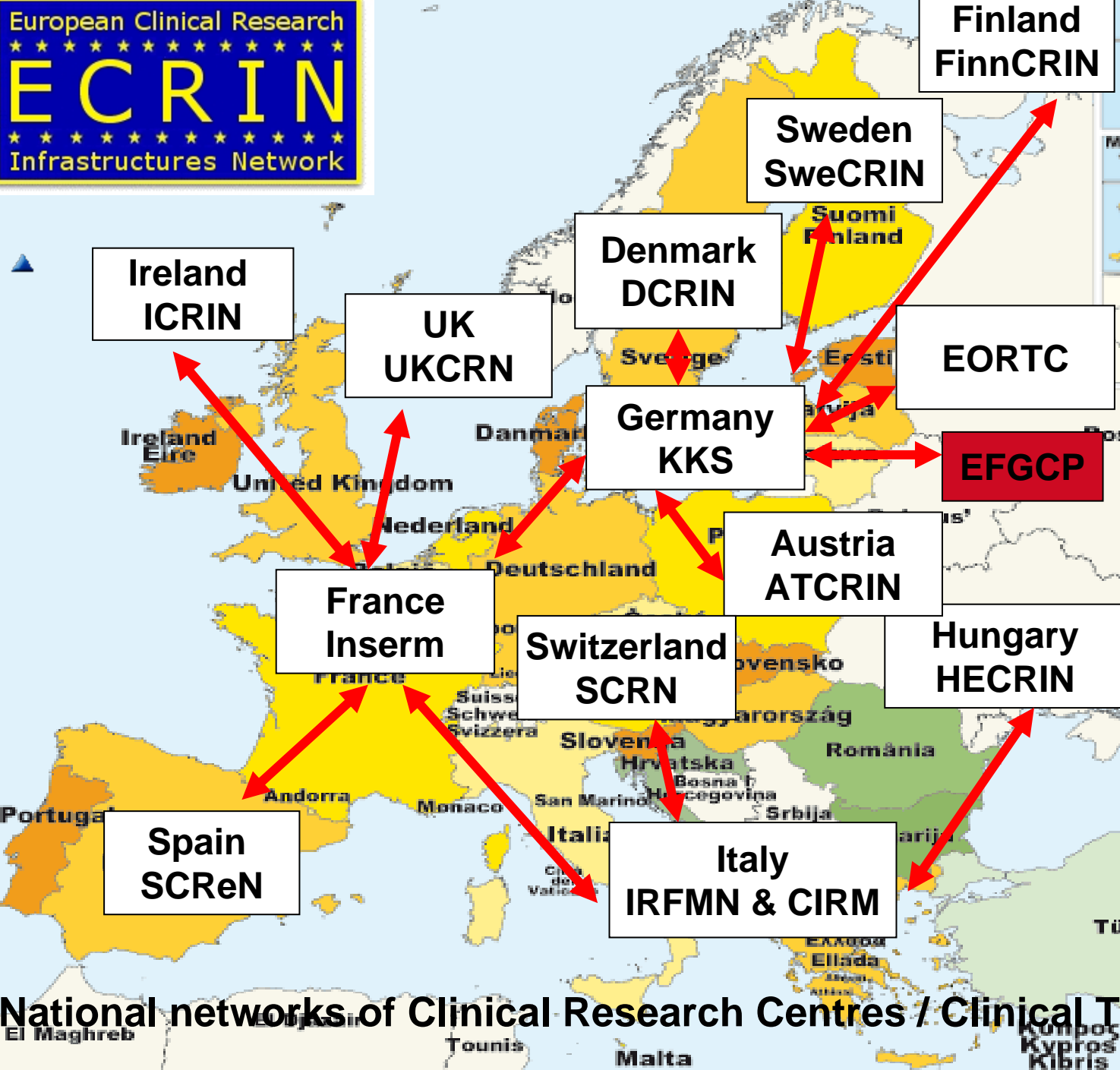
## ECRIN proposal

- **EU integration** of clinical research capacity
  - ⇒ Support to investigators
  - ⇒ Support to sponsors in multinational studies
  - ⇒ Unlocking latent potential: national networks, scientific, patients,
- Integration of public funding
  - ⇒ Avoiding duplication of studies and wasting of money
- **Harmonisation** of tools, training and practice
- Improved quality, credibility, transparency

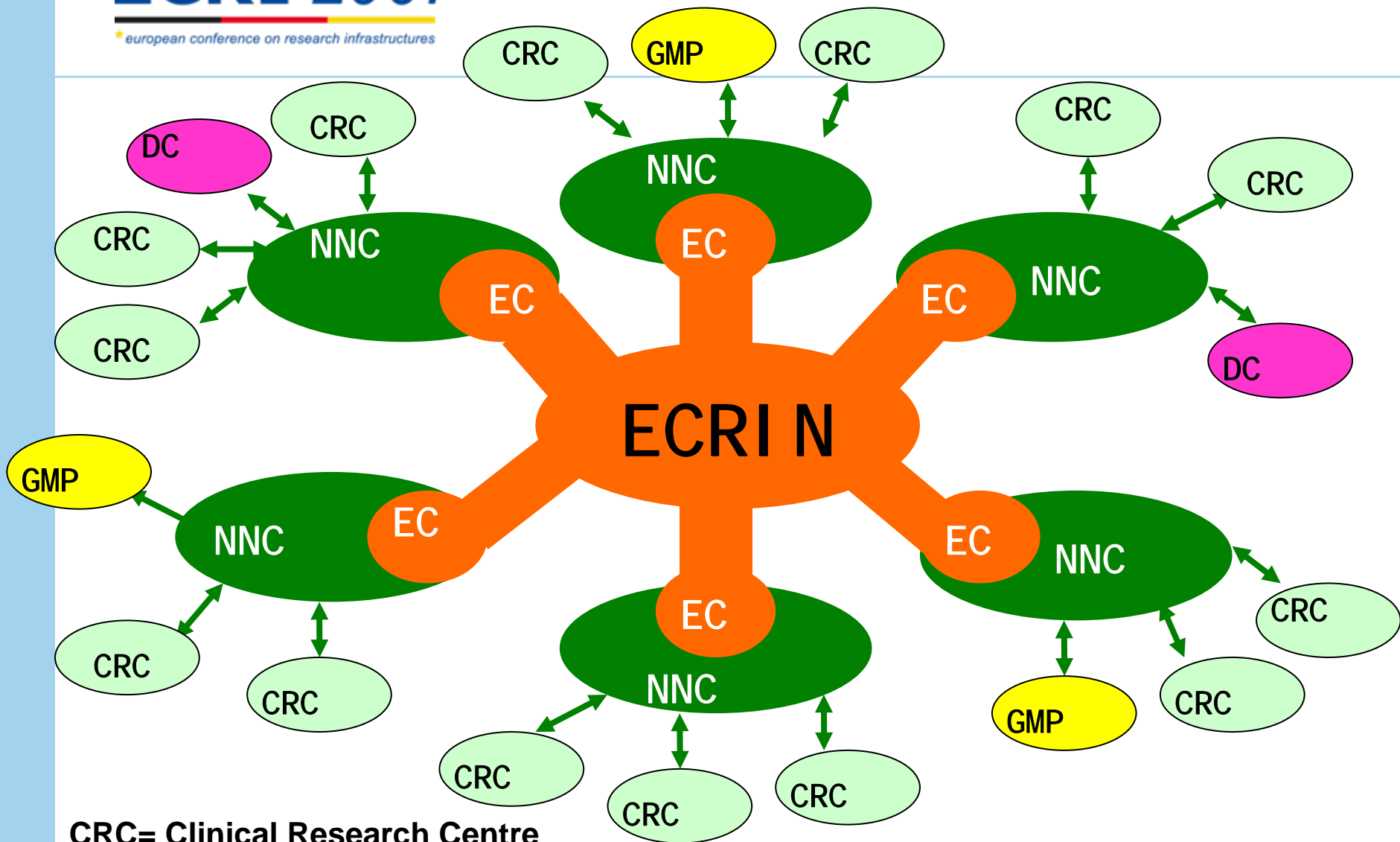
⇒ *Towards harmonisation of EU legislative systems ?*



European Clinical Research Infrastructures Network, coordinated by INSERM: Pan-European infrastructure providing services to the preparation and the conduct of multinational clinical studies, with GMP facilities for biotherapy



**National networks of Clinical Research Centres / Clinical Trial Units**



**CRC= Clinical Research Centre**  
**DC= Data centre**  
**GMP= GMP facility for biotherapy**

**EC= European Correspondent**  
**NNC= National Network Coordination**

## EU approach for GMP Facilities

### Needs:

Reinforcing clinical research and **translation** of basic research to therapy - **Innovative “non-commercial” clinical trials**

**Production** and evaluation of **innovative** therapeutic and diagnostic agents (biomarkers and biotherapy: cell & gene therapy)

**Lack of Specific financial system**

### Technical approach:

Production of new therapeutic/diagnostic agents from biotechnologies - Products for Cell and Gene therapy

Good Manufacturing Practices (*GMO dissemination regulation*), in line with national legislation, able to cooperate across the borders

**Direct links with Clinical Research Centres (CRC - ECRIN)**

## Network of Biological Resources Facilities Cohorts of Patients

### Science Case:

A European network to coordinate European Scientific programs and policies

Clinical data and follow-up of patients and Healthy volunteers

Innovative targets, biomarkers, clinical studies

Technology transfer, dissemination of knowledge, valorisation

### Technical approach:

Repositories for qualified biological samples (DNA, RNA, proteins,...), coupled to clinical data - Providers/distributors of samples within scientific project objectives

Development of QA standards for European BRCs

To store samples for the future (heritage)

Distributed facilities / centralised database

## The *challenges* for Biomedical Research infrastructures in Europe

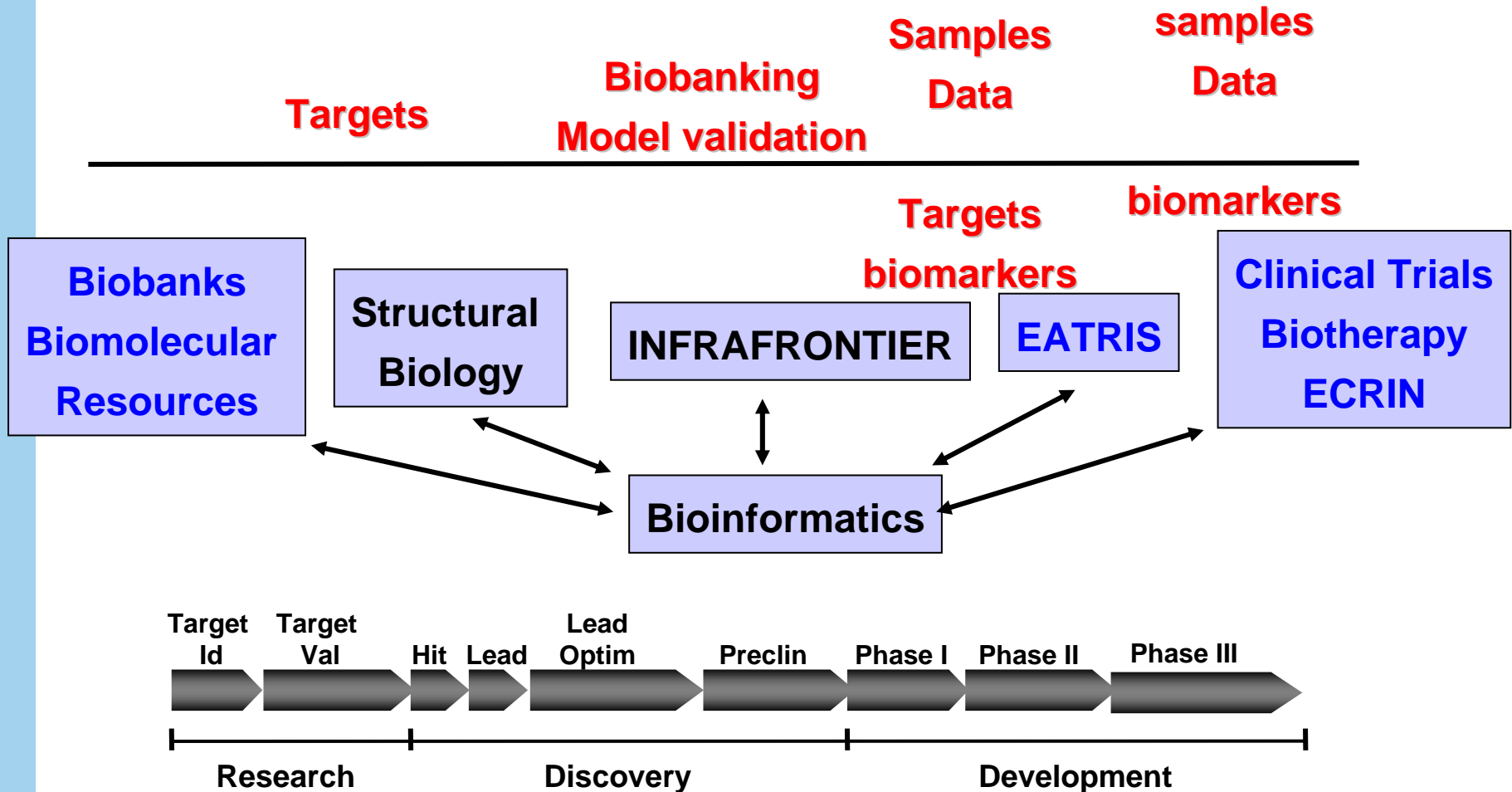
To develop an *Integrated* and *concerted* **European approach** gathering:

- ***Clinical Research Centres*** link to ***GMP*** manufacturing facilities
- ***Biological Resources centres***, including clinical data of patients and healthy volunteers - ***Cohorts*** of patients
- Management and access to ***Databases*** and ***Datacentres***
- ***Translational research centers***
- ***Animal models and facilities***: functional studies, imaging
- **IMI Joint Technology Initiative**

## First ESFRI's Roadmap priorities for *Biological and Medical Sciences*

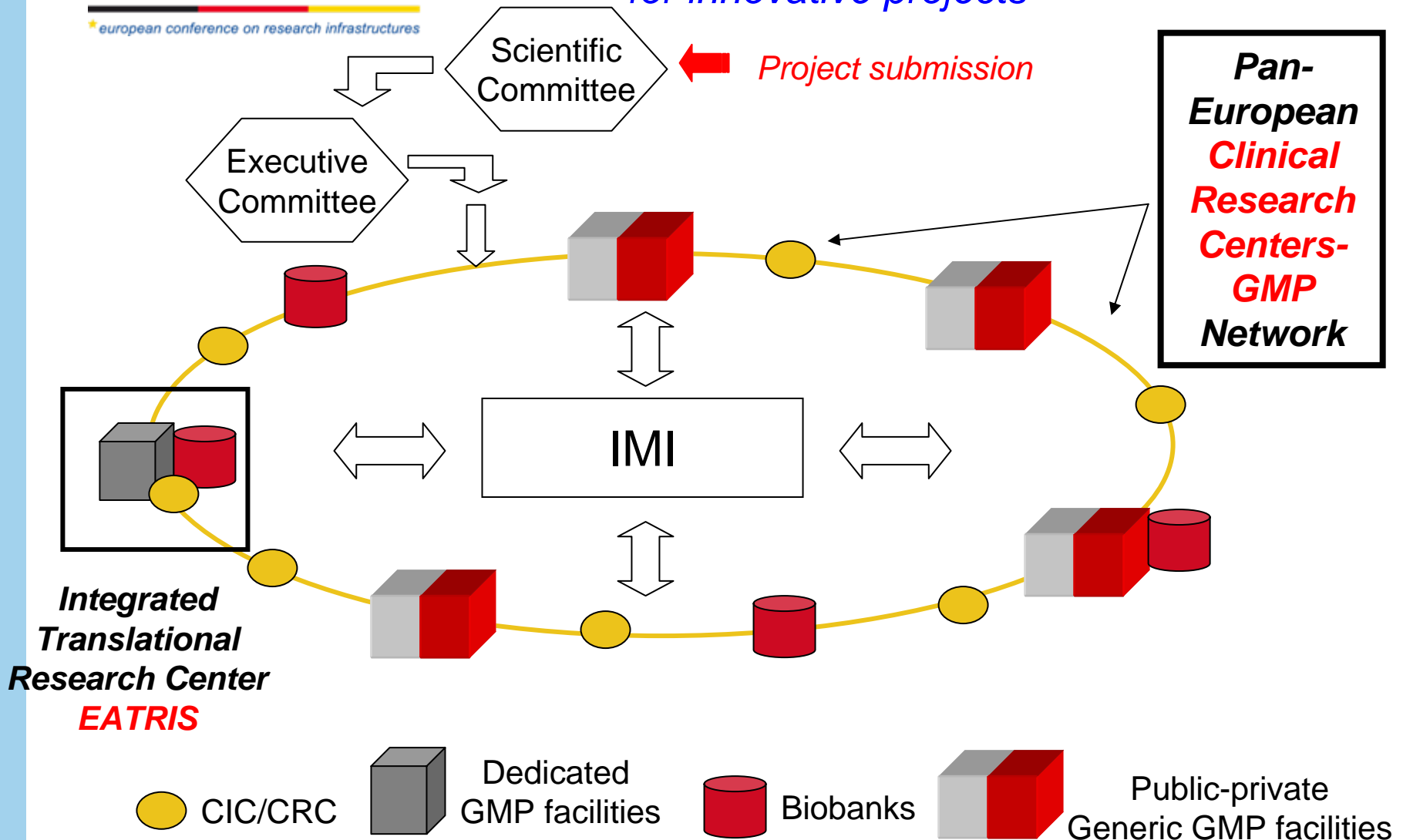
- **EATRIS** - Network of new research centres to translate basic discoveries into clinical interventions in major diseases
- **European bio-banking and Biomolecular resources** - network of existing and new biobanks (samples and data from patients and healthy persons) and molecular resources
- **ECRIN** - Network of clinical research centres, clinical trials and botherapy facilities for therapeutic innovations&
- **INFRAFRONTIER** - Distributed infrastructure for the archiving and phenotyping of mice as models for studying human diseases
- **Integrated Structural Biology Infrastructure** - Network of centres for integrated structural biology
- **Bio-informatics infrastructure** - Shared platform for data resources in the Life Sciences (EBI upgrading)

# Synergies between BMS ESFRI Infrastructures : *Concerted approach*



## Synergy : ECRIN – EATRIS - Biobanks

- ECRIN will support EATRIS projects reaching the clinical step :  
*Translational research - Clinical trials*
- GMP manufacturing facilities for clinical batches
  - Generic centres and Centres for Biotherapy / Cell therapy
  - Disease-oriented bio-pharmaceuticals products (recombinant proteins, monoclonals, oligonucleotides, vaccines...)
- Joint working groups EATRIS – Biobanks - ECRIN
  - Databases - knowledge management
  - Regulation - Legislation
  - SOPs
- Public-private partnership through the [IMI platform](#)



## Definition of a **European** Charter of research infrastructures ?

### ***Open access***

- Platforms must be open to outside scientists whatever their affiliation (public or private)
- Personnel specially devoted to the platform respond to requests for services and assistance

### ***Management***

- A scientific committee including the person in charge of the platform and off-site users and experts define services offered and methodological updates, condition of access and fees, project priorities

### ***Quality control***

- The functioning of the platform requires quality control management based on the ISO 9001 norm - version 2000

## Definition of a **European** Charter of research infrastructures ?

### ***Technological update and licencing***

- Platforms must support research of methodological nature generating publications or patents, licences, start-ups, ...

### ***Training***

- Training of students, engineers and technicians - **Support to short-mid term mobility**

### ***Evaluation***

- The group of experts will periodically undertake retrospective evaluations which results will determine subsequent funding and specific staff allocations

A **European** strategy for funding of research infrastructures ?

***To increase budget devoted by the Members-States***

***To increase and to mutualize funding from the European Union:***

***the FP7 (Capacities programme)***

***The European Structural Funds***

To ensure a **long-term action** for a future integrated “European Tool box” for Research & Innovation